

LEADING THE WAY



UNITED STATES ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY



FDA Antimicrobial Drugs Advisory
Committee Meeting

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Disclaimer

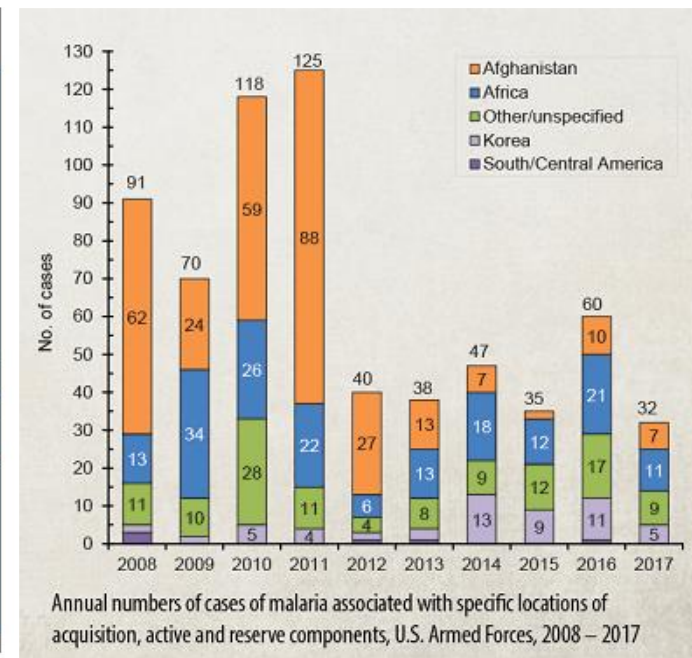
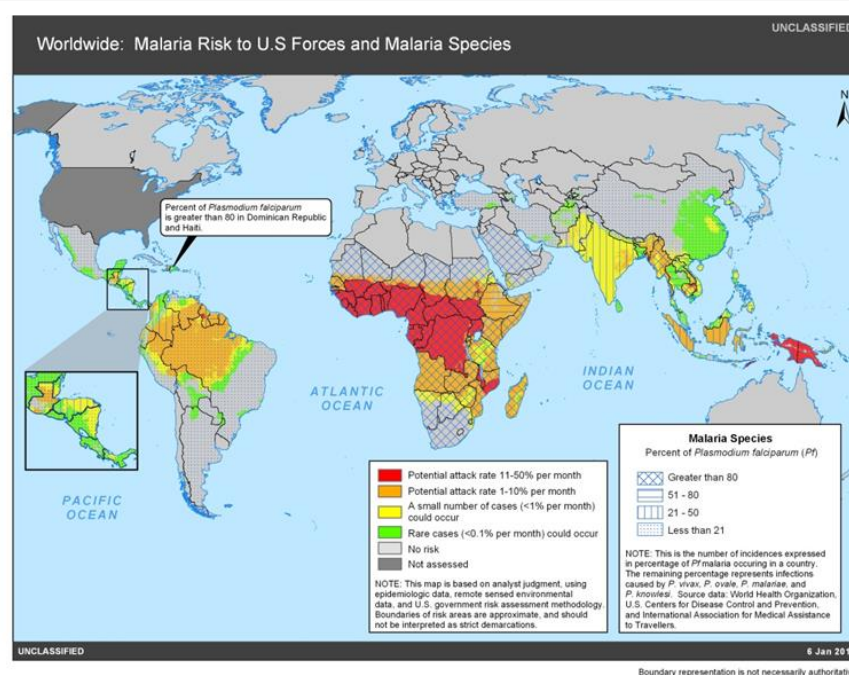
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- Discussion of specific pharmaceutical products does not reflect an endorsement of those products. USAMMDA has a Cooperative Research and Development Agreement (statute 15USC 3710a) and Exclusive License Agreement with 60 Degrees Pharmaceuticals for the development of Tafenoquine for Malaria Prophylaxis.



Malaria Risks to Military Personnel

Malaria remains the number one infectious disease threat to deployed U.S. Military

- Resistance to current anti-malarial drugs is spreading
- Potential for poor chemoprophylaxis compliance with daily dosing
 - A drug with a longer half-life provides a flexible option during challenging operational conditions
- No licensed malaria vaccine
 - Lead vaccine candidates only moderately protect against only one species of malaria (*Plasmodium falciparum*)



Source: Medical Surveillance Monthly Report, Infographic, February 2018

DoD Policy for Malaria Prophylaxis*

Current FDA Approved Malaria Prophylactic Drug	Weekly Dosing	Effective against all disease stages?	7+ days post exposure treatment required?	Comments
Doxycycline	No	No	Yes	<ul style="list-style-type: none"> ✓ FDA approved; DoD first-line drug in chloroquine resistant areas ✗ Must be taken at the same time every day ✗ Increased photosensitivity and risk of vaginitis
Atovaquone - Proguanil	No	No	Yes	<ul style="list-style-type: none"> ✓ FDA approved; DoD first-line drug in chloroquine resistant areas ✗ Resistance is developing to the drug
Mefloquine	Yes	No	Yes	<ul style="list-style-type: none"> ✓ FDA approved; for service members with intolerance or contraindications to the first-line drugs ✗ FDA boxed warning for neuro-psychiatric adverse events
<ul style="list-style-type: none"> ✗ Chloroquine - Due to widespread resistance, chloroquine is rarely used as a first line prophylaxis drug for Force Health Protection ✗ Primaquine - Although listed in the CDC Yellow Book, primaquine is not FDA approved for prophylaxis and therefore not permitted for Force Health Protection 				

*HA Policy 13-002; Joint Health Affairs Memorandum for the Guidance on Medications for Prophylaxis of Malaria; 15 April 2013



Conclusion

- Malaria is debilitating and potentially fatal, and remains the top infectious disease threat to the U.S. Military
- There is an unmet medical need for a safe and effective weekly FDA approved prophylactic drug
- Current prophylactic options are insufficient
- The U.S. Army is committed to providing safe and effective solutions to protect the Warfighter

